AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

10.85 Advisory opinions.
10.90 Food and Drug Administration regulations, recommendations, and agreements.
10.95 Participation in outside standard-setting activities.
10.100 Public calendar.
10.105 Representation by an organization.
10.110 Settlement proposals.
10.115 Good guidance practices.

Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

10.200 Scope.
10.203 Definitions.
10.204 General.
10.205 Electronic media coverage of public administrative proceedings.
10.206 Procedures for electronic media coverage of agency public administrative proceedings.

AUTHORITY: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

SOURCE: 44 FR 22323, Apr. 13, 1979, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 10 appear at 68 FR 24879, May 9, 2003.

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws which the Commissioner of Food and Drugs administers.

(b) If a requirement in another part of title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) References in this part and parts 12, 13, 14, 15, and 16 to *publication*, or to the day or date of publication, or use of the phrase *to publish*, refer to publication in the FEDERAL REGISTER unless otherwise noted.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989; 69 FR 17290, Apr. 2, 2004]

§ 10.3 Definitions.

(a) The following definitions apply in this part and parts 12, 13, 14, 15, 16, and 19:

Act means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

Administrative action includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral.

Administrative file means the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations.

Administrative record means the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action.

Agency means the Food and Drug Administration.

Chief Counsel means the Chief Counsel of the Food and Drug Administration.

Commissioner means the Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health and Human Services, or the Commissioner's designee.

Department means the U.S. Department of Health and Human Services.

Division of Dockets Management means the Division of Dockets Management, Office of Management and Operations of the Food and Drug Administration, U.S. Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Ex parte communication means an oral or written communication not on the public record for which reasonable prior notice to all parties is not given, but does not include requests for status reports on a matter.

FDA means the Food and Drug Administration.